UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EVY GRU, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. AXSOME THERAPEUTICS, INC., HERRIOT TABUTEAU, NICK PIZZIE, MARK JACOBSON, CEDRIC O'GORMAN, and KEVIN LALIBERTE, Defendants.	Case No.: 1:22-cv-3925-LGS **AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

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Co-Lead Plaintiffs Evy Gru and Santoshanand Thakkar ("Plaintiffs"), individually and on behalf of all others similarly situated, by Plaintiffs' undersigned attorneys, for Plaintiffs' complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiffs and Plaintiffs' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiffs' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Axsome Therapeutics, Inc. ("Axsome" or "Company"), analysts' reports and advisories about the Company, interviews of confidential witnesses, and information readily obtainable on the Internet. Plaintiffs believe that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.[1]

I. INTRODUCTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Axsome securities between December 30, 2019, and April 22, 2022, both dates inclusive ("Class Period"), seeking to recover damages caused by Defendants' violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act").

2. On April 25, 2022, Axsome, a New York-based biopharmaceutical company that develops novel therapies for central nervous system ("CNS") disorders, disclosed that due to chemistry, manufacturing, and controls ("CMC") issues, the United States Food & Drug Administration ("FDA") would reject its new drug application ("NDA" or "Application") for

[1] Emphases herein are added unless noted otherwise below.

AXS-07—a product candidate for the acute treatment of migraine. The Company stated that the FDA had identified CMC issues during its review of the Application. Defendants disclosed too that they expected the FDA to issue a Complete Response Letter ("CRL" or "Response")[2] "with respect to this NDA on or about the Prescription Drug User Fee Act target action date of April 30, 2022."[3] At the very least, these developments would substantially delay approval while Axsome addressed the CMC issues the FDA identified and resubmitted the AXS-07 NDA. In response to this news, Axsome's stock price plummeted approximately 22%.

3. AXS-07 is one of Axsome's five products from its core CNS portfolio. From at least late 2019, Defendants knew or recklessly disregarded that CMC issues plagued the Company's development of AXS-07. Part of an NDA includes a section on the drug's chemistry, manufacturing, and controls. These CMC issues are an essential part of the drug development process. They ensure that the manufacturing process for the drug produces a product that is consistent with the specifications that were used in a more limited capacity during clinical trials.

4. For example, according to senior clinical trial personnel, one fatal CMC issue was that a contract manufacturing organization—a third party with whom Axsome contracted to produce AXS-07—had equipment problems throughout 2021 and leading up to the FDA review deadline in 2022. Accordingly, Axsome was simply unable to manufacture the drug for an extended duration during this crucial period of time during the FDA's review of its Application for AXS-07.

[2] In a CRL the FDA informs the applicant that it is declining to approve an NDA. The FDA sends a CRL after it has completed the review of the NDA. A CRL is therefore a definitive statement that the NDA was not sufficient to support approval of the drug under consideration

[3] A target action date is the date under the Prescription Drug User Fee Act by which the FDA plans to review an NDA.

5. Indeed, Defendants knew that the necessary supply of AXS-07 for a clinical trial that Axsome had planned was unavailable, causing Axsome to delay the trial multiple times. Even in early 2022, the manufacturer remained unable to resolve its equipment problems. Given that the supply disruption delayed this trial—and manufacturing partners therefore could not produce AXS-07 even in limited supplies for trials—Defendants recklessly disregarded the CMC issues that ultimately caused the FDA to issue the CRL. Axsome's complete inability to manufacture AXS-07 was a severe manufacturing problem relevant to the "chemistry, ***manufacturing***, and controls" portion of the AXS-07 Application.

6. Also, according to clinical trial personnel, Defendants prioritized profit over patients, cutting corners during the drug development process in a rush to meet milestones. Indeed, the CMC issues with Axsome's AXS-07 NDA were the Company's second NDA in short succession for which the FDA found CMC issues. The Company also experienced CMC problems when it was attempting to submit an NDA for another one of its five core CNS products, AXS-05. Those issues also caused delays and put Defendants on notice of CMC issues with its Applications.

7. Even as Defendants knew of or recklessly disregarded the AXS-07 CMC issues, they misrepresented them to investors. ***First***, Defendants affirmatively discussed CMC issues as supporting the AXS-07 NDA and did not mention the ongoing manufacturing problems with AXS-07. Defendants even repeated a continued refrain in Axsome's SEC filings throughout the Class Period that the Company's suppliers would be capable of providing sufficient quantities of their product when the Company's supplier for AXS-07 was failing to do so.

8. ***Second***, Axsome promoted an unrealistic timeline for the submission of an NDA for AXS-07. Defendants constantly represented to investors that the NDA for AXS-07 would be filed in 2020, despite knowing of the significant CMC problems in the development process.

Rather than submit the NDA for AXS-07 by the end of 2020, as Defendants had repeatedly promised, Axsome did not submit the NDA until June 2021.

9. ***Third***, throughout the Class Period, Defendants promoted the outcomes of AXS-07's clinical trials and Axsome's supposedly positive discussions with the FDA about those results as supporting the timely approval of its Application for the drug. It was materially misleading for Defendants to promote the likely approval of AXS-07 based on these factors while omitting the material CMC problems that plagued the development of AXS-07—to the point where Axsome could not even manufacture the drug while its Application was under review.

10. These materially false and misleading statements harmed Axsome's investors because the Company's stock price sank when Axsome revealed the truth about the CMC problems with AXS-07—including falling 22% on April 25, 2022, after the Company revealed the FDA's concerns that caused it to deny the AXS-07 NDA.

II. JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

13. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Axsome is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

14. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

15. Plaintiff Gru, as set forth in the previously filed Certification (ECF No. 14-3), acquired the Company's securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the truth described below.

16. Plaintiff Thakkar, as set forth in the previously filed Certification (ECF No. 10-2), acquired the Company's securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the truth described below.

17. Defendant Axsome is a Delaware corporation with principal executive offices located at 22 Cortlandt Street, 16th Floor, New York, New York 10007. Axsome's common stock trades in an efficient market on the NASDAQ under the trading symbol "AXSM".

18. Defendant Herriot Tabuteau, M.D. ("Tabuteau") founded Axsome in 2012 and has served as its Chief Executive Officer and Chairman of the Board of Directors since that time.

19. Defendant Nick Pizzie ("Pizzie") has served as Axsome's Chief Financial Officer since May 2018.

20. Defendant Mark Jacobson ("Jacobson") has served as Axsome's Chief Operating Officer since March 2020. Before then, he served as the Company's Senior Vice President of Operations since September 2017 and has been employed at the Company since April 2014.

21. Defendant Cedric O'Gorman ("O'Gorman") served as Axsome's Senior Vice President of Clinical Development and Medical Affairs from September 2017 to September 2021.

22. Defendant Kevin Laliberte ("Laliberte") served as Axsome's Executive Vice President of Product Strategy from January 2021 to December 2021.

23. Defendants Tabuteau, Pizzie, Jacobson, O'Gorman, and Laliberte are sometimes referred to herein as the "Individual Defendants."

24. The Individual Defendants possessed the power and authority to control the contents of Axsome's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Axsome's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Axsome, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

25. Axsome and the Individual Defendants are collectively referred to herein as "Defendants."

IV. SUBSTANTIVE ALLEGATIONS

A. Background

26. Axsome is a biopharmaceutical company based in New York City engaging in the development of novel therapies for CNS conditions that have limited treatment options.

27. Defendant Tabuteau founded Axsome in January 2012. The Company went public through an initial public offering on the NASDAQ stock exchange on November 19, 2015.

28. Two of Axsome's five core products from its CNS portfolio are its AXS-07 and AXS-05 treatments.

29. AXS-07 is a novel, oral, rapidly absorbed, multi-mechanistic, and investigational medicine for the acute treatment of migraine. AXS-05 is a treatment of major depressive disorder ("MDD").

30. AXS-05 and AXS-07 are the first two products for which Axsome submitted NDAs to the FDA. They were, therefore, the Company's most immediate and direct chances to make a profit for its investors. The Company's first Annual Report that it issued during the Class Period described AXS-05 and AXS-07 as the first two drugs in its "core CNS portfolio."

31. Axsome sought FDA approval for AXS-07 and AXS-05 under the FDA's 505(b)(2) regulatory development pathway. Under that pathway, companies submit an NDA "that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference."

32. Market analysts consistently rated the Company positively based on the value that AXS-07 was expected to add to the Company according to the positive clinical trial results that Axsome reported for AXS-07 at the beginning of the Class Period. For example, on December 30, 2019, SunTrust Robinson Humphrey published a favorable report based on the Company's positive MOMENTUM trial data. In this report, the analyst stated that "we think AXS-07 is approvable based on data reported this morning." The primary two factors that contributed to the report's $100 price target for Axsome stock were the values of AXS-05 and AXS-07. Cantor Fitzgerald similarly published a December 30, 2019 report in which it raised its 12-month price target for Axsome from $104 per share to $125 per share based on the positive trial data for AXS-07.

33. Even as Axsome researched and developed therapies, it explained in its Annual Reports during the Class Period, it did "not currently own or operate any manufacturing facilities for the clinical or commercial production of our drug candidates." Instead, it used "independent contract manufacturing organizations, or CMOs," to manufacture its drugs and supply its clinical trials. Axsome explained that it "conduct[ed] periodic quality audits of their facilities," concluding that Axsome's CMOs "***will be capable of providing sufficient quantities***" of product "***to meet our clinical trial supply needs***."

B. AXS-07

34. During the Class Period, Defendants consistently told investors that Axsome's Application for AXS-07 was proceeding smoothly along a rapid timeline. Axsome promoted positive test results and feedback from the FDA that Defendants represented as supporting the AXS-07 Application. Axsome, however, delayed its submission of the NDA. Then, after submitting the NDA, Axsome announced that the FDA found CMC problems with the Application. This negative feedback, at the very least, would lead to substantial delays in Axsome being able to resubmit an NDA for AXS-07. As will be described further below, all along, Defendants knew or recklessly disregarded the CMC problems that existed for AXS-07.

35. Axsome describes AXS-07 as "a novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine under development for the acute treatment of migraine." AXS-07 consists of what the Company calls "MoSEIC™, or Molecular Solubility Enhanced Inclusion Complex," including meloxicam and rizatriptan. Axsome describes this as a "combination drug," which is "a single drug product that consists of two or more active ingredients, with each component making a contribution to the claimed effect of the drug."

36. "Meloxicam is a long-acting nonsteroidal anti-inflammatory drug, or NSAID" with "potent pain-relieving effects." AXS-07 uses Axsome's proprietary MoSEIC™ technology to

"substantially increase" the speed at which meloxicam takes effect "while potentially maintaining durability of action."[4] Rizatriptan is included in AXS-07 because it "may reduce the release of inflammatory mediators from trigeminal nerves" and "is approved as a single agent for the acute treatment of migraine."

37. In February 2019, Axsome reached an agreement with the FDA for the Company's planned MOMENTUM (Maximizing Outcomes in Treating Acute Migraine) Phase 3 trial of AXS-07. The Company represented that the FDA agreed that the protocol for the MOMENTUM trial (e.g., entry criteria, dose selection, endpoints) "adequately address objectives that, if met, will support filing of an NDA of AXS-07 for the indication of acute treatment of migraine in adults with or without aura."[5]

38. In August 2020, Axsome announced a successful Pre-NDA meeting with the FDA for AXS-07 for the acute treatment of migraine.

39. Axsome initiated the MOMENTUM study in March 2019. On December 30, 2019, Axsome announced that AXS-07 had met its two regulatory co-primary endpoints in the

[4] Axsome also explains that "AXS-07 consists of MoSEIC™, or Molecular Solubility Enhanced Inclusion Complex, meloxicam and rizatriptan. Meloxicam is a long-acting nonsteroidal anti-inflammatory drug, or NSAID, with COX-2, an enzyme involved in inflammation and pain pathways, preferential inhibition and potent pain-relieving effects. However, standard meloxicam has an extended time to maximum plasma concentration, or Tmax, which delays its onset of action. AXS-07 utilizes our proprietary MoSEIC™ technology to substantially increase the solubility and speed the absorption of meloxicam while potentially maintaining durability of action. Meloxicam is a new molecular entity for migraine enabled by our MoSEIC™ technology."

[5] A Phase 3 clinical trial is the final stage of study before a new drug is submitted to the FDA for approval through an NDA. Phase 1 typically involves a very small number of participants (usually 100 or fewer) and tests a drug's overall safety and dosage. Phase 2 typically tests the drug on a larger group of people (up to a few hundred) to assess its efficacy and further assess its safety. A drug that passes Phase 1 and Phase 2 can then be subject to Phase 3 trials. Phase 3 trials are the most rigorous, as they typically test the drug on a larger group of people in a more controlled manner, and possibly for longer duration, to further assess the drug's efficacy in comparison to current treatment options and safety.

MOMENTUM study. In particular, Axsome announced that it "achieved co-primary and key secondary endpoints and significantly improved migraine pain, freedom from most bothersome symptoms, and sustained pain freedom, in the MOMENTUM study."

40. The Company also told investors that the results from the MOMENTUM study supported the filing of an NDA for AXS-07 for "the acute treatment of migraine"; that "[b]ased on FDA feedback, Axsome believes that MOMENTUM will be the only efficacy trial required to support an NDA filing for AXS-07 for the acute treatment of migraine"; and that "Axsome plans to file the NDA in the second half of 2020."

41. Defendant Tabuteau stated in Axsome's press release that day that "[w]ith these positive [Phase 3] results, we look forward to filing an NDA for AXS-07 in the acute treatment of migraine in 2020."

42. Over the course of the Class Period, Axsome told the market that AXS-07 was proceeding along this timeline and would be a major milestone in the Company reaching the commercial stage of its key products.

43. Axsome also conducted a second Phase 3 trial on AXS-07 called INTERCEPT. The Company told investors this study would bolster the strength of its NDA even further. The Company initiated the INTERCEPT study in October 2019.

44. In April 2020, Axsome announced that AXS-07 achieved the co-primary endpoints in the INTERCEPT study. Axsome then proceeded to promote both the MOMENTUM and INTERCEPT studies as supporting the Company's NDA for AXS-07.

45. In addition to what Axsome described as its positive results from MOMENTUM and INTERCEPT, the Company conducted a "Phase 3, open-label, long-term safety extension study of AXS-07 . . . to further support the NDA filing," as the Company explained in a May 8,

2020 press release. The Company called this the MOVEMENT (Multimechanistic Treatment Overtime of Migraine Symptoms) trial and stated that it would support the planned NDA for AXS-07.

46. For example, on August 10, 2020, Axsome stated in connection with its results for the second quarter of 2020, that "***we remain on track to submit the NDA for AXS-07 for the acute treatment of migraine in the fourth quarter***. To that end, we have completed enrollment in the Phase 3 open-label safety extension trial of AXS-07 in migraine, which we call the MOVEMENT study to support the planned NDA filing. As we move towards the filing of our NDA[] in the fourth quarter . . . for AXS-07, our commercial team is focused on launch-readiness activities to ensure successful commercial execution."

47. Despite consistently assuring investors that AXS-07 was on track to have its NDA submitted in 2020 based on its successful results from its MOMENTUM, INTERCEPT, and MOVEMENT trials, Axsome surprised investors by announcing, on November 5, 2020 (in connection with the Company's third quarter 2020 results) that "Axsome now plans to submit the [AXS-07] NDA to the FDA in the first quarter of 2021, versus previous guidance of the fourth quarter of 2020, to allow for inclusion of supplemental manufacturing information to ensure a robust submission package."

48. At this point, however, Axsome portrayed this issue arising from information related to the manufacturing of AXS-07 as a minor delay that could be solved by submitting more information to the FDA. Axsome did not give any indication that there were actual problems with the manufacturing process for AXS-07 that might result in the FDA's rejection of its NDA. Rather, Defendants continued to mislead investors by assuring them that the "inclusion of supplemental

manufacturing information" would address any concerns and "ensure a robust submission package."

49. For example, even after the Company's November 5, 2020 announcement of a delay in the AXS-07 NDA, Axsome stated in its Form 10-Q for the first quarter of 2021, filed with the SEC on May 10, 2021, that "[w]e plan to submit an NDA for AXS-07 for the acute treatment of migraine supported by the positive results from the MOMENTUM and INTERCEPT trials. An open-label, long-term, safety study of AXS-07 in patients with migraine known as the MOVEMENT trial has also been completed. In the MOVEMENT trial, administration of AXS-07 resulted in rapid, and substantial relief of migraine pain and associated symptoms and was well tolerated with long term dosing."

50. Axsome did not end up submitting its NDA for AXS-07 until June 2021—months after its already-delayed timeline of the first quarter of 2021 that the Company announced on November 5, 2020.

51. On September 14, 2021, Axsome announced that the FDA had "accepted for filing the Company's New Drug Application (NDA) for AXS-07 for the acute treatment of migraine, and has set a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2022 for the NDA."[6]

52. Defendant Tabuteau stated in this press release that "[t]he FDA's acceptance of the NDA for AXS-07 is an important milestone for Axsome as it brings us closer to potentially making this multi-mechanistic treatment available to migraine patients in need." Defendants added that "[w]e look forward to continued interactions with the FDA during the review process" and that

[6] The PDUFA was first passed in 1992. It requires that companies pay a fee when they submit NDAs in order to enable the FDA to timely review NDAs. The standard timeline for the FDA to complete a review under the PDUFA is 10 months and is 6 months for priority reviews.

the NDA for AXS-07 "is supported by results from two Phase 3 randomized, double-blind, controlled trials of AXS-07 in the acute treatment of migraine, the MOMENTUM and INTERCEPT trials."

1. The FDA's Negative Feedback Regarding AXS-07

53. On April 25, 2022, before the market opened, Axsome announced that on April 22, 2022, the Company was informed by the "FDA that chemistry, manufacturing, and controls ('CMC') issues identified during the FDA's review of the Company's New Drug Application ('NDA') for its AXS-07 product candidate for the acute treatment of migraine are unresolved. Based upon the time remaining in the NDA review cycle, the Company expects to receive a Complete Response Letter ["CRL"] with respect to this NDA on or about the Prescription Drug User Fee Act target action date of April 30, 2022."

54. The market reacted very negatively to this unexpected setback for AXS-07. On this news, Axsome's stock price fell $8.60 per share, or 21.99%, to close at $30.50 per share on April 25, 2022.

55. On April 25, 2022, William Blair published a report that described this news as "obviously disappointing," noting that the stock is down 24% premarket and that this would cause a substantial delay in the approval of AXS-07.

56. Axsome's April 25, 2022, announcement that the FDA found CMC issues with AXS-07 indicates that the FDA had previously communicated its concerns to the Company. This announcement notes that the issues that the FDA had identified were "unresolved" as of April 22, 2022. In other words, the FDA had given Axsome a chance to resolve these issues, but the Company failed to address them. If the FDA had not told Axsome about these problems previously, the FDA would have simply stated that it would be issuing a CRL because of issues that it

identified with the NDA. Instead, the resolution period that the FDA referenced indicates that it had given Axsome a chance to resolve these issues, but the Company failed to address these defects. Despite the FDA previously informing Axsome about these issues with the AXS-07 NDA, this was the first time that Axsome publicly disclosed that the FDA had any concerns whatsoever with the Application.

57. Moreover, as described further below, regardless of whether the FDA had communicated these CMC issues to Axsome before April 22, 2022, they existed—and posed an extreme risk to the pending NDA—much earlier in the development process for AXS-07.

58. Axsome then announced on May 2, 2022, that it received the Response from the FDA for the AXS-07 NDA. The Company stated that "[t]he CRL did not identify or raise any concerns about the clinical efficacy or safety data in the NDA, and the FDA did not request any new clinical trials to support the approval of AXS-07. The principal reasons given in the CRL relate to [CMC] considerations. The CRL identified the need for additional CMC data pertaining to the drug product and manufacturing process. Axsome believes that the issues raised in the CRL are addressable and intends to provide potential timing for a resubmission following consultation with the FDA." In other words, Axsome could not give any indication at that point in time as to when it might be able to resubmit an NDA for AXS-07.

2. Axsome's Development of AXS-07 Was Plagued by CMC Issues

59. Part of an NDA includes completing a section on the drug's chemistry, manufacturing and controls (CMC). This relates to the company's process for manufacturing the product. It also confirms that the product that is being tested in a limited capacity in the approval process is consistent with the product that will be manufactured and sold commercially, in much larger quantities, following FDA approval. CMC requirements ensure that the manufacturing

process produces a safe and effective drug that is consistent with the drug that was used in clinical trials and is the subject of an NDA.

60. For example, a contract research organization (CRO) that provides testing and research support services in the pharmaceutical industry explains that "[a]fter clinical trials the scale up process must ensure that the larger batches of product are the same and meet the same specifications as the drug tested in the clinical trials. After the manufacturing process is qualified, lot release and in process testing will continue to take place."[7]

61. CMC issues are a crucial part of the FDA approval process because even if a drug is safe and effective in theory, it must also be so in the real world. A drug should not be sold to the public if it is not being manufactured in the way it is supposed to be.

62. Axsome's development of AXS-07 was plagued by CMC issues. After the FDA issued the CRL for the AXS-07 NDA, Defendant Tabuteau stated on the Company's May 2, 2022 earnings call for the first quarter of 2022 that "[t]he principal reason given in the CRL relate to chemistry, manufacturing and controls or CMC considerations. The CRL identified the need for additional CMC data pertaining to the drug product and manufacturing process. We believe that all the issues raised in the CRL are addressable." While Tabuteau continued to promote the efficacy and safety aspects of its clinical trials for AXS-07, he was not able to provide any update as to its submission of a new NDA other than to say that "[w]e intend to provide potential timing for a resubmission following consultation with the FDA."

63. Later, on this May 2, 2022, call, in a response to a request for more information about the CRL for AXS-07, Defendant Jacobson explained that "as we mentioned, the questions and the request for additional information, they principally relate to drug product and the

[7] https://pacificbiolabs.com/cmc-chemistry-manufacturing-and-controls.

manufacturing process. So just a reminder that AXS-07 incorporates our MoSEIC technology, with a novel technology that Axsome developed." He concluded, "[a]nd so that does increase the complexity of the manufacturing process, the MoSEIC technology. And so we understand the basis for many of the questions, and we do believe they're addressable."

64. Tabuteau also noted, conciliatorily—now that the public was aware of CMC problems with AXS-07—that "we fully understand the reasons why the [FDA] would want to make sure that any new technology, any new manufacturing process is fully vetted."

65. The most that Tabuteau could say as to timing was that "[w]hat we're looking to do is to meet with the FDA as expeditiously as possible. That's a Type A meeting. We want to make sure that we get our ducks in a row prior to requesting that meeting and getting a date. Once we have that meeting and we get feedback from the agency. In other words, we confirm exactly what it is that should go into the resubmission that we can have success, then we'll be in a position to provide you with updated guidance on timing." He also noted "that we do expect that once we resubmit that the resubmission would likely be treated as a Class II resubmission, leading to a six-month review."

66. In addition, in response to a question about whether the CRL addressed any other issues beyond CMC questions, Tabuteau stated that it dealt "principally with all CMC" but "there was one item related to non-clinical, which was just our quest for additional information, which we believe we can provide. So for us, the real focus is this is a stand [stet] focus is CMC." In other words, the CRL also raised a non-CMC issue that Axsome did not fully describe.

67. While Defendants have been vague in their public disclosures as to the nature of the CMC problems that the FDA identified with AXS-07, a former employee, who was a Senior

Clinical Trial Manager at Axsome from July 2019 to February 2022 (Confidential Witness 1 ("CW 1")), provided details of what the issues were.

68. CW 1 reported to the Executive Director of Clinical Research (Amanda Jones), the Director of Clinical Operations (Cheryl Askew), and the Senior Director of Clinical Operations (Caroline Streicher) at various points during CW 1's tenure at the Company. CW 1 was based in Axsome's New York City office.

69. In early 2021, CW 1 was tasked to start managing a new study to provide additional data for AXS-07 that was scheduled to begin at the end of April 2021. The purpose of this study was to support the marketing of AXS-07 with additional published data. The study initially got delayed until August 2021 and then until November 2021.

70. The reason for this delay was that Axsome did not have a sufficient supply of AXS-07 for the study. The supply of AXS-07 that Axsome had available was nearing its expiration date, so the Company needed to produce more for the study.

71. According to CW 1, around August 2021, Fang Liu, Axsome's Senior Director of Supply Chain for AXS-07, told CW 1 directly that one of the contract manufacturing organizations that Axsome contracted with to produce AXS-07 was having equipment problems and was therefore unable to manufacture the drug.

72. As the months passed, Axsome continued to wait for the necessary supply of AXS-07. When it continued to not receive the drugs, the Company delayed the study again, this time planning to conduct it in early 2022. At that point, Liu told CW 1 again that the manufacturer was ***still*** having equipment problems that it was not able to resolve. These problems therefore persisted at least from April 2021 through when CW 1 left the Company in February 2022.

73. According to CW 1, Axsome used one vendor to supply meloxicam and another vendor to supply rizatriptan, which are the two active ingredients in AXS-07. Axsome then used a third vendor to combine the two products to make AXS-07. It was this third vendor that was having problems with the equipment used to combine the two drugs. Liu told CW 1 that Axsome was waiting for the vendor to fix the equipment and was not trying to find a new vendor to manufacture the drug.

74. CW 1 stated that the CMC issues that the FDA identified in its CRL for AXS-07 involved this contract manufacturing organization's equipment problem.

75. Furthermore, CW 1 stated that Axsome's executive management would have known about the CMO's equipment problems.

76. In addition to being attested to by CW 1, this knowledge of senior management comports with the manufacturing problems that CW 1 described. CW 1 observed that the Company was not able to produce one of its core drug candidates, which was one of only two drugs for which the Company was in the process of submitting NDAs. This delay went on for an extended period of time and caused a trial that Axsome was working on to be delayed indefinitely. Axsome's senior management would have known of this delay that made the Company completely unable to manufacture, or conduct studies on, one of its main products for an extended period of time.

77. Moreover, the timing of this delay in Axsome's ability to manufacture AXS-07 coincided with the FDA's review of the NDA for the drug. Axsome delayed the submission of the NDA from the end of 2020 to the first quarter of 2021, and then delayed it again, to the second quarter of 2021. This timing aligns with the delay in the ability of Axsome's CMO to manufacture AXS-07 for a study that was initially scheduled to begin in April 2021, but then ended up being delayed indefinitely over the course of the FDA's review of the Application.

78. In fact, on the Company's earnings call for the fourth quarter of 2020, held on March 1, 2021, an analyst asked why the AXS-07 NDA submission had been pushed back to the second quarter of 2021. Defendant Tabuteau responded that "[w]ith regard [AXS-]07 and the NDA filing the team remains on track to complete the filing by the end of the quarter. However, we are waiting on one vendor report which will slip into very beginning of the second quarter and that's the reason[.]" While Tabuteau did not disclose any information about the vendor's actual problems with manufacturing AXS-07 or give investors any indication that such problems existed, this statement about the timing of the vendor's report corroborates CW 1's description of when the vendor's manufacturing problems arose.

79. This manufacturing problem with AXS-07 was particularly material because the CMO's inability to manufacture enough of the drug even for limited clinical trials demonstrates Axsome's inability to produce AXS-07 on the timeline and scale necessary for commercializing it.

80. Moreover, the manufacturing problem with AXS-07 stemmed from the particularly complex nature of the drug, which required a third vendor focused specifically on combining the component parts of AXS-07 that were themselves obtained from two separate vendors.

81. All of these factors show that Axsome's extended problems with manufacturing AXS-07 were not just run-of-the mill equipment problems, but rather, were severe obstacles that prevented the Company from being able to successfully manufacture AXS-07 for commercial purposes.

82. Defendants' disclosure of the delay in submitting the AXS-07 Application, followed by the CRL, confirms, in material part, the information from CW 1. For example, Axsome announced on November 5, 2020, that it was delaying its submission of its NDA for AXS-

07 "to allow for inclusion of supplemental manufacturing information to ensure a robust submission package." On the Company's earnings call that day, an analyst asked for Defendants to "provide more specifics on what manufacturing data related to the MoSEIC platform will be added for AXS-07." Defendant Tabuteau gave the following response:

> Great. So with regards to the additional manufacturing information, this is a standard information when you manufacture additional batches. So we continue to manufacture additional batches of drugs. And while we already have very long-term stability data on other batches, we think that because of the unique nature of the delivery technology, this can only help to make the submission robust and assure that there are no hiccups during review.

83. This explanation—while not disclosing the truth because Tabuteau falsely represented that Axsome was able to continue manufacturing AXS-07—indicates that the Company was continuing to work on the "long-term stability" of the manufacturing capacity it needed to commercialize AXS-07. This information that Defendant Tabuteau gave on the November 5, 2020 earnings call also did not disclose the truth because Tabuteau described the additional information that Axsome needed as "standard" and not concerning. But his responses show that the problem that CW 1 observed with Axsome's CMO for AXS-07 being able to manufacture the product is consistent with the topics that Tabuteau discussed—even if he did so in a coded way so as not to reveal the problems that Axsome's vendor was having manufacturing AXS-07.

84. In addition, as noted above, Defendants disclosed on May 2, 2022, that the CRL related "to the drug product and manufacturing process."

85. As Berenberg Capital Markets explained in an April 25, 2022 report, the CMC problems with AXS-07 "may be due to inadequacies with the manufacturing process," such as "the facility's manufacturing process" or "quality control of the drug," including "consistency of the drug product," "inconsistency between drug bunches," or "supply shortages, resulting in the

company's inability to find a replacement for the material in need."[8] These types of problems are precisely what CW 1 observed.

86. Moreover, as Defendants disclosed on May 2, 2022, the CRL was not even focused exclusively on CMC issues because those were only the "principal reasons" that formed the basis for the CRL.

87. In addition to the specific issue related to the manufacturing of AXS-07, CW 1's observations reflect a more systemic problem with Axsome's quality controls. CW 1 commented that the Company's executive leadership appeared to prioritize profit over patients and that they "cut corners." In addition, the Company seemed to always be in a rush to meet milestones.

88. And, as described further below, CW 1 observed a separate issue in a study for AXS-05 caused by a poorly written testing protocol that allowed unqualified patients to participate in the relevant clinical study and resulted in Axsome receiving a Form 483 from the FDA for its failure to exclude unqualified patients from participating in the study.

C. AXS-05

89. Defendants should have been on heightened notice for CMC issues with AXS-07 because the Company had just experienced a similar issue with its other main product, AXS-05 for the treatment of MDDs. Investors also expected that Axsome would not make the same mistake

[8] The full language from the Berenberg report stated that the CMC problems with AXS-07 "may be due to inadequacies with the manufacturing process, either related to 1) the facility's manufacturing process; or 2) quality control of the drug. Facility-related issues include missing documentation, lack of material/in-process controls, or required modifications to existing protocol (typically a significantly long process). Potential drug quality issues tie to consistency of the drug product and its safety and stability, including impurities in the product, inconsistency between drug bunches, or inadequate stability of the product (may take up to 24 months to prove). An additional potential CMC issue could be supply shortages, resulting in the company's inability to find a replacement for the material in need."

twice in a row and were shocked by the Company's repeated CMC failures on two consecutive NDAs in short succession.

90. For example, in an April 25, 2022 report, Cantor Fitzgerald lowered its price target for Axsome as a result of the news about the FDA's denial of the AXS-07 NDA, calling it "déjà vu," explaining that "[t]he Company ran into regulatory issues for its NDA of '05 for MDD as the agency had identified two deficiencies related to analytical methods in the CMC which needed to be addressed prior to the FDA taking action on the NDA. Although we had previously indicated that we believe these CMC issues have been resolved, our conviction that that is the case is now decreased as ***CMC deficiencies appear to be a persistent issue plaguing the company***."

91. Cowen also advised investors to "[r]ecall that the company had previously indicated that the FDA expected to complete the required inspection of the AXS-07 contract manufacturing facility prior to the April 30 PDUFA date and the company had not communicated any other delays with the review prior to today, thus the update comes as a disappointment. Additionally, given the history of the AXS-05 review in MDD, investors are likely not to take kindly to any uncertaint[y] between the company and the FDA."

92. Also on April 25, 2022, Morgan Stanley published a note titled "Surprise Setback for AXS-07 in Migraine Presents Additional Pipeline Uncertainty." The note explained that "the surprise setback for AXS-07 is likely to increase investor uncertainty regarding prospects for the AXS-05 NDA - particularly given the hurdle faced by both applications are CMC related." As a result of this news, Morgan Stanley stated that "[w]e would expect significant pressure on AXSM following the update on AXS-07. We continue to remain on the sidelines with an EW rating, and note that our PT for AXSM is currently under review." It also described one of the primary risks that the Company faced as being an "FDA rejection of Axsome's NDA for AXS-07 in migraine."

93. Similarly, the SMBC Group commented in a note that day, titled "More Storm Clouds Gathering with Pending Rejection for AXS-07 in Migraine," that Axsome's stock suffered a 22% drop that day "on the negative news" and that "[w]e view the stock move as appropriate." This news would result in a "sizable delay" for the approval and launch of AXS-07, which led SMBC Group to lower its price target for Axsome from $45 per share to $29 per share. SMBC Group also commented that given Axsome's prior problems with AXS-05, regardless of whether the CMC problem with AXS-07 was "related to some of the problems that have been encountered previously with" AXS-05, "***troubles in manufacturing seem to be a recurring theme with AXSM's drug candidates***."

94. Axsome developed AXS-05 for the treatment of MDD, among other conditions. The Company states that it "believe[s] there is a substantial need for new, more effective treatments for this large, underserved patient population." It describes AXS-05 as "a novel, oral, investigational NMDA receptor antagonist with multimodal activity."[9]

95. In July 2020, Axsome announced a positive pre-NDA meeting with the FDA regarding the Company's planned NDA submission of AXS-05 for the treatment of MDD. Axsome submitted the NDA for AXS-05 for MDD in early 2021.[10]

96. On April 26, 2021, Axsome announced that the FDA accepted the NDA for AXS-05 for MDD for priority review. This means that the FDA accelerated the review time from the standard 10 months to 6 months, making the Prescription Drug User Fee Act target action date August 22, 2021. The Company stated that "[t]he NDA is supported by results from two

[9] An NMDA receptor is a type of neurological receptor.

[10] Axsome announced on March 1, 2021, that it submitted the NDA earlier that year, but did not provide the specific date.

randomized, double-blind, controlled trials of AXS-05 in patients with a confirmed diagnosis of moderate to severe MDD."

97. Then, Axsome surprised investors by announcing before the market opened on August 9, 2021—less than two weeks before the August 22, 2021, PDUFA date for AXS-05—that the FDA found "deficiencies" with the NDA. The Company stated in a press release that day that "[a]s part of the ongoing review of our NDA for AXS-05, the FDA recently notified us that they have identified deficiencies that preclude labeling discussions at this time." The Company added, "[w]e are attempting to learn the nature of these deficiencies with the goal of addressing them, however, this development may lead to a delay in the potential approval of AXS-05."

98. The August 9, 2021, press release continued, explaining that "[o]n July 30, 2021, the Company received a letter from the FDA stating that it has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time." With respect to FDA approval, the Company concluded, "[t]he letter stated further that the notification does not reflect a final decision on the information under review. The letter did not state what the deficiencies are."[11]

99. On the Company's earnings call that day, Defendant Tabuteau acknowledged that "[a]lthough the [FDA] letter stated that the notification does not reflect a final decision on the information under review, this development may lead to a delay in the potential approval of AXS-05. We will keep you informed as we learn more."

[11] The FDA explains that post-marketing requirements and commitments are "studies and clinical trials that sponsors conduct after approval to gather additional information about a product's safety, efficacy, or optimal use." While these studies are not completed until after approval, they may be set out as part of the approval process.

100. Investors reacted very negatively to this news because it meant that, at the very least, there would be a substantial delay in the approval of AXS-05. For example, Guggenheim Securities issued a report warning investors that "AXS-05 approval now in question after FDA letter noting 'deficiencies' in the NDA filing."

101. That day, on August 9, 2021, Axsome's stock price fell by 46.5%, from a closing price of $51.16 per share the day before to a closing price of $27.37 that day.

102. Following this time, Defendants were on heightened notice that the FDA might not approve Axsome's Applications because of CMC issues with the drug candidates. At the time, AXS-07 was the Company's only other product to have had an NDA submitted. Moreover, while Axsome had the opportunity to fix the CMC issues with AXS-05 under its original NDA, the CMC issues with AXS-07 were even more serious because they led to the FDA issuing a CRL denying the drug's Application. Defendants should have been extra attuned to CMC problems following the CMC issues that the FDA raised with AXS-05.

103. On August 23, 2021, the Company updated investors, stating that the FDA "informed the Company in a teleconference on August 20, 2021, that its review of the new drug application (NDA) for AXS-05 for the treatment of major depressive disorder would not be completed by the PDUFA target action date of August 22, 2021. The FDA did not request additional information from the Company, and the review of the application is ongoing."

104. On November 8, 2021, during Axsome's earnings call for the third quarter of 2021, Defendant Tabuteau disclosed that the FDA "recently informed us of two deficiencies related to analytical methods in the chemistry, manufacturing and control section of the NDA [for AXS-05], which must be addressed prior to the FDA taking action on the NDA."

105. CW 1 (who was a Senior Clinical Trial Manager at Axsome from July 2019 to February 2022), noted other deficiencies that the FDA identified with AXS-05 due to a "poorly written" testing protocol. The sloppy testing protocol did not clearly indicate to the clinical trial sites that patients who did not complete their data entry requests during clinical trial visits by at least 80 percent, were not eligible to participate in the study. Due to the lack of clarity, clinical testing sites allowed patients who did not meet this requirement to participate in the study. A clinical trial site for AXS-05, that was audited by the FDA, received a Form 483 from the agency in November 2021 for not excluding patients from the study who failed to meet this criteria.

106. A Form 483 "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. . . . The FDA Form 483 notifies the company's management of objectionable conditions."[12]

107. The FDA ultimately approved AXS-05 on August 19, 2022. While the market reacted positively to this news, it came one year after AXS-05 initial PDUFA date of August 22, 2021. This significant delay left investors with substantial uncertainty during that time. Investors who sold their Axsome securities in the interim because they lost hope after learning of the problems with the development of AXS-05 suffered substantial losses.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

108. Throughout the Class Period, Defendants made materially false and misleading statements regarding Axsome's business and operations. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Axsome's development of AXS-07

[12] https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions.

was plagued by CMC problems (including that Axsome's CMO was unable to produce sufficient supply of AXS-07 even for limited clinical trials) that Defendants were required to disclose in the context of discussions of CMC issues or positive disclosures about clinical trial results and assurances as to the filing of, and FDA approval for, the AXS-07 NDA; (ii) as a result, Axsome was unlikely to submit the AXS-07 NDA on its initially represented timeline; (iii) these CMC problems remained unresolved after Axsome submitted its NDA for AXS-07; (iv) as a result, Defendants knew or were severely reckless in not knowing that the FDA would delay or even reject approval of the AXS-07 NDA because of the unresolved material CMC issues.

109. The Class Period begins on December 30, 2019, when Axsome issued a press release during pre-market hours, announcing positive results from AXS-07's Phase 3 MOMENTUM trial for the treatment of migraine. This press release was signed by Defendant Jacobson and was filed with a Form 8-K with the SEC that was signed by Defendant Tabuteau.

110. The press release stated, in relevant part, that "[t]he positive results on both co-primary endpoints along with the demonstration of component contribution support the filing of an NDA for AXS-07 in the acute treatment of migraine"; that "[b]ased on FDA feedback, Axsome believes that MOMENTUM will be the only efficacy trial required to support an NDA filing for AXS-07 for the acute treatment of migraine"; and that "Axsome plans to file the NDA in the second half of 2020."

111. This December 30, 2019 press release also quoted Defendant Tabuteau as stating that "[t]hese data have potentially important implications for patient care based on the high rate of inadequate response to and patient dissatisfaction with current treatments. With these positive results, we look forward to filing an NDA for AXS-07 in the acute treatment of migraine in 2020."

112. The statements referenced in ¶¶ 109-11 above were materially false and/or misleading for the reasons set forth in ¶ 108(i)-(ii) and (iv), including because they misrepresented the timeline for filing an NDA for AXS-07, and the likelihood of success of that NDA, in light of the CMC problems that plagued the development of AXS-07.

113. On March 12, 2020, Axsome issued a press release by Defendant Jacobson and filed with the SEC on a Form 8-K signed by Defendant Tabuteau, reporting the Company's fourth quarter and full year 2019 results. The press released stated that "[t]he positive results from the MOMENTUM trial support an NDA filing for AXS-07 in the acute treatment of migraine, which is anticipated in the fourth quarter of 2020"; and that "[t]o support the planned NDA filing of AXS-07 in the acute treatment of migraine, enrollment in a Phase 3 open-label, long-term safety extension study of AXS-07 is ongoing."

114. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's fourth quarter and full year 2020 results. In his prepared remarks, Defendant Tabuteau stated:

> The positive results from the MOMENTUM trial support an NDA filing for AXS-07 in the acute treatment of migraine and we remain on track to file this NDA in the second half of 2020. With . . . two planned NDA filings Axsome is on track to transition to commercial stage potentially as early as next year.

115. The statements referenced in ¶¶ 113-14 above were materially false and/or misleading for the reasons set forth in ¶ 108(i)-(ii) and (iv), including because they misrepresented the timeline for filing an NDA for AXS-07, and the likelihood of success of that NDA, in light of the CMC problems that plagued the development of AXS-07.

116. Also on March 12, 2020, Axsome filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended

December 31, 2019 (the "2019 10-K"). The 2019 10-K was signed by Defendants Tabuteau and Pizzie.

117. The 2019 10-K contained certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 ("SOX"), and Statements of Principal Executive Officers pursuant to 18 U.S.C. Section 1350, as adopted by SOX, signed by Defendants Tabuteau and Pizzie. These certifications attested that the 2019 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report"; fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended"; and that "[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

118. The 2019 10-K stated that "[i]n February 2019, we reached agreement with the FDA under an SPA [*i.e.*, a Special Protocol Assessment] for the design, endpoints, and statistical approach of the planned MOMENTUM (Maximizing Outcomes in Treating Acute Migraine) Phase 3 trial of AXS-07 in the acute treatment of migraine. Based on FDA feedback during this SPA process, Axsome believes that only one Phase 3 trial may be needed for the approval of AXS-07."

119. The 2019 10-K also stated that "[t]he MOMENTUM study was conducted pursuant to an SPA with the FDA. The SPA provides agreement that the overall MOMENTUM trial design (e.g., entry criteria, dose selection, endpoints) and planned analysis adequately address objectives that, if met, will support filing of an NDA of AXS-07 for the indication of acute treatment of migraine in adults with or without aura."

120. The statements referenced in ¶¶ 118-19 above were materially false and/or misleading for the reasons set forth in ¶ 108(i)-(ii) and (iv), including because they misrepresented the timeline for filing an NDA for AXS-07, and the likelihood of approval for the NDA, in light of the CMC problems that plagued the development of AXS-07.

121. In addition, the 2019 10-K stated, when describing Axsome's contract manufacturing organizations:

> We conduct manufacturing activities under individual purchase orders with independent contract manufacturing organizations, or CMOs, to supply our clinical trials. We conduct periodic quality audits of their facilities. ***We believe that our existing suppliers of our product candidate active pharmaceutical ingredients and finished products will be capable of providing sufficient quantities of each to meet our clinical trial supply needs.*** Other CMOs may be used in the future for clinical supplies and, subject to approval, commercial manufacturing.

122. The statements referenced in ¶ 121 above were materially false and/or misleading for the reasons set forth in ¶ 108(i) and (iv), including because Axsome's CMOs were not "capable of providing sufficient quantities of" AXS-07 to meet the Company's "clinical trial supply needs."

123. The 2019 10-K provided only boilerplate representations regarding potential CMC issues that could materialize for any NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing. This boilerplate language stated that "the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional . . . [CMC], or other data and information."

124. Similarly, the 2019 10-K stated in supremely general terms that "[d]uring the course of review, the FDA may also request or require additional chemistry, manufacturing, and control (CMC), or other data and information, and the development and provision of these data and information may be time consuming and expensive."

125. The statements referenced in ¶¶ 123-24 above were materially false and/or misleading for the reasons set forth in ¶ 108(i) and (iv), including because they raised the

possibility of future CMC issues in connection with an NDA while failing to disclose the CMC problems that already plagued the development of AXS-07.

126. The 2019 10-K also provided only boilerplate representations regarding Axsome's CMOs, stating that "[i]f the manufacturers upon whom we rely fail to produce our product candidates in the volumes that we require on a timely basis, . . . we may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues."

127. The 2019 10-K similarly stated that "[i]f our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively."

128. The statements referenced in ¶¶ 126-27 above were materially false and/or misleading for the reasons set forth in ¶ 108(i) and (iv), including because they raised the possibility of future manufacturing issues with Axsome's CMOs while failing to disclose the actual manufacturing problem that already existed with Axsome's CMO for AXS-07.

129. On April 6, 2020, Axsome issued a press release by Defendant Jacobson, and filed with the SEC on a Form 8-K signed by Defendant Tabuteau, announcing that AXS-07 had met its co-primary endpoints in its INTERCEPT Phase 3 trial. This was the Company's second Phase 3 trial for the treatment of migraine. That press release quoted Defendant Tabuteau at stating:

> With INTERCEPT and the previously completed MOMENTUM Phase 3 trial in patients with a history of inadequate response to prior acute treatments, AXS-07 has now been evaluated in two positive well-controlled trials . . . . INTERCEPT strengthens our planned NDA for AXS-07 in the acute treatment of migraine, which remains on track to be submitted to the FDA in the fourth quarter.

130. The statements referenced in ¶ 129 above were materially false and/or misleading for the reasons set forth in ¶ 108(i)-(ii) and (iv), including because they misrepresented the timeline for filing an NDA for AXS-07, and the role of clinical trials in supporting the NDA, in light of the CMC problems that plagued the development of AXS-07.

131. On May 8, 2020, Axsome issued a press release by Defendant Jacobson, and filed with the SEC on a Form 8-K signed by Defendant Tabuteau, reporting the Company's first quarter 2020 results, stating:

> As we move towards the submission of two NDAs in the fourth quarter . . . one for AXS-07 in migraine, our commercial team is focused on launch-readiness activities to ensure successful commercial execution.
>
> * * *
>
> Axsome remains on track to submit an NDA for AXS-07 in the acute treatment of migraine to the FDA in the fourth quarter of 2020. The NDA is supported by positive efficacy results from the MOMENTUM and INTERCEPT trials. A Phase 3, open-label, long-term safety extension study of AXS-07 is ongoing to further support the NDA filing.

132. The statements referenced in ¶ 131 above were materially false and/or misleading for the reasons set forth in ¶ 108(i)-(ii) and (iv), including because they misrepresented the timeline for filing an NDA for AXS-07, and the likelihood that the FDA would approve the NDA for AXS-07, in light of the CMC problems that plagued the development of AXS-07.

133. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's first quarter 2020 results. On that call, in response to an analyst question

regarding whether there "[i]s . . . any new clinical data, including . . . CMC activities" for the Company's NDAs, Defendant Tabuteau stated:

> With regards to CMC activities, there are registration batches which are being manufactured now. A good thing for us is that we have been manufacturing our clinical trial supply at commercial scale and also at the same CMO that we're using for commercial production. So, there's no scale up that needs to be done.
> Now, with regards to manufacturing and any kind of science to it, there's always tweaks and experimentation, but I would say that there is no rate-limiting step and there is no extensive experimentation. This is simply manufacturing our registration batches for regulatory purposes.

134. The statements referenced in ¶ 133 above were materially false and/or misleading for the reasons set forth in ¶ 108(i) and (iv), including because they misrepresented the status of CMC issues with AXS-07.

135. On May 11, 2020, Axsome filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2020 (the "1Q2020 10-Q"). The 1Q2020 10-Q was signed by, and contained SOX certifications substantively the same as those referenced in ¶ 117 above from, Defendants Tabuteau and Pizzie.

136. The 1Q2020 10-Q stated that "[w]e have completed two Phase 3 trials of AXS-07 for the acute treatment of migraine, which we refer to as the MOMENTUM and INTERCEPT trials. AXS-07 achieved the co-primary endpoints in both the MOMENTUM and INTERCEPT trials. We plan to submit an NDA for AXS-07 for the acute treatment of migraine supported by the positive results from the MOMENTUM and INTERCEPT trials."

137. In addition, the 1Q2020 10-Q provided only boilerplate representations regarding potential CMC issues that could materialize for any NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing. This boilerplate language stated that "in connection with the [CMC] data necessary for our NDA filings, we will need to conduct stability studies and provide stability data to establish appropriate retest or expiration dating period"; and that "[d]uring

the course of review, the FDA may also request or require additional CMC, or other data and information, and the development and provision of these data and information may be time consuming and expensive."

138. The statements referenced in ¶¶ 136-37 above were materially false and/or misleading for the reasons set forth in ¶ 108(i), (iv), including because they misrepresented the likelihood that the FDA would approve the NDA for AXS-07, and the extent to which clinical trials supported an NDA for AXS-07, in light of the CMC problems that plagued the development of AXS-07.

139. The 1Q2020 10-Q also provided the same boilerplate representations regarding third-party CMOs that were provided in the 2019 10-K that are referenced in ¶¶ 126-27 above, which were false and misleading for the reasons described in ¶ 128 above.

140. On August 10, 2020, Axsome issued a press release by Defendant Jacobson, and filed with the SEC on a Form 8-K signed by Defendant Tabuteau, reporting the Company's second quarter 2020 results, stating:

> Axsome remains on track to submit an NDA for AXS-07 in the acute treatment of migraine to the FDA in the fourth quarter of 2020. The NDA is supported by positive efficacy results from the MOMENTUM and INTERCEPT trials.
>
> Enrollment has been completed in the MOVEMENT (Multimechanistic Treatment Overtime of Migraine Symptoms) Phase 3 open-label, long-term safety trial to support the planned NDA filing of AXS-07 in the acute treatment of migraine. More than 700 patients have been enrolled, approximately 450 of whom have been treated with AXS-07 for at least 6 months to date.

141. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's second quarter 2020 results. In his prepared remarks, Defendant Tabuteau stated:

> Over the past several months, we continued to advance our . . . AXS-07 product candidate[] towards NDA submission[] in . . . migraine[.]

* * *

> [W]e remain on track to submit the NDA for AXS-07 for the acute treatment of migraine in the fourth quarter. To that end, we have completed enrollment in the Phase 3 open-label safety extension trial of AXS-07 in migraine, which we call the MOVEMENT study to support the planned NDA filing. As we move towards the filing of our NDA[] in the fourth quarter . . . for AXS-07, our commercial team is focused on launch-readiness activities to ensure successful commercial execution.

142. The statements referenced in ¶¶ 140-41 above were materially false and/or misleading for the reasons set forth in ¶ 108(i)-(ii), (iv), including because they misrepresented the timeline for filing an NDA for AXS-07, and the likelihood that the FDA would approve the NDA for AXS-07, in light of the CMC problems that plagued the development of AXS-07.

143. Also on August 10, 2020, Axsome filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2020 (the "2Q2020 10-Q"). The 2Q2020 10-Q was signed by, and contained SOX certifications substantively the same as those referenced in ¶ 117 above from, Defendants Tabuteau and Pizzie

144. The 2Q2020 10-Q contained substantially the same statements referenced in ¶¶ 136-39 above from the 1Q2020 10-Q, that were false and misleading for the same reasons described therein.

145. On November 5, 2020, Axsome issued a press release by Defendant Jacobson, and filed with the SEC on a Form 8-K signed by Defendant Tabuteau, reporting the Company's third quarter 2020 results. This press release disclosed that "Axsome now plans to submit the [AXS-07] NDA to the FDA in the first quarter of 2021, versus previous guidance of the fourth quarter of

2020, to allow for inclusion of supplemental manufacturing information to ensure a robust submission package."[13]

146. While this statement started to reveal CMC issues with AXS-07, it did not reveal the nature or extent of those issues. To the contrary, Defendants continued to assure investors about the success of AXS-07. For example, the November 5, 2020 press release continued that "[p]re-submission activities for the Company's NDA for AXS-07 in the acute treatment of migraine are progressing with major NDA-related items on track for completion by year-end."

147. In addition, the November 5, 2020 press release quoted Defendant Tabuteau as stating that "[o]ver the past several months, we continued to advance our . . . AXS-07 product candidate[] towards NDA submission[] in . . . migraine, and intensified our commercial launch readiness activities," and that "[w]e anticipate an active next few months as we complete our NDA submission[] for . . . AXS-07[.]"

148. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's third quarter 2020 results. In his prepared remarks, Defendant Tabuteau reiterated that the Company was taking steps to ensure a robust AXS-07 NDA submission, particularly with respect to the drug's manufacturing, stating:

> Switching now to our migraine program with AXS-07. The major [NDA] related items are on track for completion by year end. We now plan to submit the NDA in the first quarter of 2021 versus previous guidance of the fourth quarter of 2020 in order to allow for inclusion of supplemental manufacturing information. We believe that this approach will enhance the robustness of our submission.

149. On the same call, in response to multiple analyst questions regarding the additional manufacturing information that Axsome submitted to the FDA for the AXS-07 NDA, Defendants

[13] Axsome did not end up meeting even this delayed timeline and ended up submitting its NDA for AXS-07 in June 2021.

Tabuteau and Jacobson assured investors that the additional information was just to ensure a robust submission and did not reflect any manufacturing issues. For example, an exchange with one analyst read as follows:

> **[SVB Leerink Analyst]**
>
> And then the second issue was the – for [AXS-]07. You talked about the NDA in the first quarter, including extra manufacturing information. Can you give us kind of the same sense of confidence that, as - you know, my first question, with respect to what's going on here, may give us a little bit more color and how much we're on top of it. And it's definitely going to be not any more delayed than that?
>
> **[Defendant] Tabuteau**
>
> * * *
>
> So with regards to AXS-07, this is a little bit of a different situation. Here, this is a situation whereby by the end of the year, we will have completed all the major activities, which are needed to file our NDA. And we're on track to do that. And because of the unique manufacturing, behind the MoSEIC technology, we want to make sure that we have as robust as possible of a submission package.
>
> So we continue to generate data. And the question is, how much do you include. And since, you know, we will be having some data in the early part of the year, we'd love to be able to include that in the package.
>
> But to provide some additional color on that, I'm going to turn it over to [Defendant] Jacobson.
>
> **[Defendant] Jacobson**
>
> Good morning, Marc. So just want to be clear, this is not the result of the manufacturing or stability issue or anything like that. Exactly as [Defendant Tabuteau] said, that we will have data available, that we think would add to the submission given us a novel delivery technology. And so that will just allow us to make the package as robust as possible.

150. In response to a similar question from another analyst, Defendant Tabuteau again downplayed issues with respect to AXS-07's manufacturing:

> **Unidentified Analyst**

> This is Miguel on the line for Joon. Could you provide more specifics on what manufacturing data related to the MoSEIC platform will be added for AXS-07?
>
> * * *
>
> **[Defendant] Tabuteau**
>
> Great. So with regards to the additional manufacturing information, this is a standard information when you manufacture additional batches. So we continue to manufacture additional batches of drugs. And while we already have very long-term stability data on other batches, we think that because of the unique nature of the delivery technology, this can only help to make the submission robust and assure that there are no hiccups during review.

151. The statements referenced in ¶¶ 145-50 above were materially false and/or misleading for the reasons set forth in ¶ 108(i)-(ii) and (iv), including because they misrepresented the timeline for filing an NDA for AXS-07 and the status of CMC issues with AXS-07.

152. Also on November 5, 2020, Axsome filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2020 (the "3Q2020 10-Q"). The 3Q2020 10-Q was signed by, and contained SOX certifications substantively the same as those referenced in ¶ 117 above from, Defendants Tabuteau and Pizzie

153. The 3Q2020 10-Q contained substantially the same statements referenced in ¶¶ 136-39 above from the 1Q2020 10-Q, that were false and misleading for the same reasons described therein.

154. On March 1, 2021, Axsome issued a press release by Defendant Jacobson, and filed with the SEC on a Form 8-K signed by Defendant Tabuteau, reporting the Company's fourth quarter and full year 2020 results. That press release quoted Defendant Tabuteau as stating that "[w]e had successful pre-NDA meetings with the FDA . . . for AXS-07 in migraine" and "are nearing submission of the NDA for AXS-07 in the acute treatment of migraine, which is expected early in the second quarter." Similarly, Tabuteau assured investors that "[o]ur focus for the

remainder of the year will be on the regulatory activities surrounding these NDAs, [and] launch readiness to ensure a successful transition to commercialization[.]"

155. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's fourth quarter and full year 2020 results. On that call, and in response to an analyst's question regarding why the AXS-07 NDA submission was pushed back to second quarter 2021, Defendant Tabuteau stated: "With regard [AXS-]07 and the NDA filing the team remains on track to complete the filing by the end of the quarter. However, we are waiting on one vendor report which will slip into very beginning of the second quarter and that's the reason[.]"

156. The statements referenced in ¶¶ 154-55 above were materially false and/or misleading for the reasons set forth in ¶ 108(i) and (iv), including because Axsome was not able "to ensure a successful transition to commercialization" of AXS-07 in light of the CMC issues that prevented it from being able to manufacture the drug.

157. Also on March 1, 2021, Axsome filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K was signed by, and contained SOX certifications substantively the same as those referenced in ¶ 117 above from, Defendants Tabuteau and Pizzie.

158. The 2020 10-K contained substantially the same statements regarding CMOs and Axsome's CMC practices referenced in ¶¶ 121-28 above from the 2019 10-K and ¶¶ 136-38 above from the 1Q2020 10-Q, that were false and misleading for the same reasons described therein. The 2020 10-K

159. On May 10, 2021, Axsome hosted a conference call with investors and analysts to discuss the Company's first quarter 2021 results. In response to an analyst question regarding "what the gating factors are in terms of getting th[e AXS-07 NDA] submission into the FDA"

given that Axsome had pushed back its regulatory timeline multiple times, Defendant O'Gorman stated, in relevant part: "With regards to AXS-07, we're very much on track to file the NDA this quarter, as we've previously stated, and there really isn't any update there. The team is working diligently to make sure that we have a timely, but also a quality filing."

160. The statements referenced in ¶¶ 159 above were materially false and/or misleading for the reasons set forth in ¶ 108(i) and (iv), including because Axsome would not be able to submit a "quality filing" in light of the CMC problems that plagued the development of AXS-07.

161. Also on May 10, 2021, Axsome filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2021 (the "1Q2021 10-Q"). The 1Q2021 10-Q was signed by, and contained SOX certifications substantively the same as those referenced in ¶ 117 above from, Defendants Tabuteau and Pizzie.

162. The 1Q2021 10-Q contained substantially the same statements referenced in ¶¶ 136-39 above from the 1Q2020 10-Q, that were false and misleading for the same reasons described therein.

163. On August 9, 2021, Axsome issued a press release by Defendant Jacobson, and filed with the SEC on a Form 8-K signed by Defendant Tabuteau, reporting the Company's second quarter 2021 results. That press release quoted Defendant Tabuteau, who noted that although the FDA had identified deficiencies with an NDA for the Company's AXS-05 product candidate, "[o]ur other programs continue to advance" and "[w]e successfully filed our NDA for AXS-07 for the acute treatment of migraine in the second quarter[.]"

164. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's second quarter 2021 results. In response to an analyst question regarding whether AXS-07 is manufactured at the same facility as AXS-05, Defendant Jacobson stated:

> So for the manufacturing process for AXS-07, that actually is a bit more complicated and there are two facilities that we utilized for the manufacturer of the drug product. The drug -- the API's are also available under open DMF too in the U.S. And of the two facilities that we used for drug product manufacturing, one of them is the same that we used for AXS-05.

165. The statements referenced in ¶¶ 163-64 above were materially false and/or misleading for the reasons set forth in ¶ 108(i) and (iii)-(iv), including because they misrepresented the status of CMC issues with AXS-07 and discussed the topic of the manufacturing of AXS-07 while failing to disclose the CMC issues that plagued the development of the drug.

166. Also on August 9, 2021, Axsome filed with the SEC a quarterly report on Form 10-Q, reporting the Company's financial and operating results for the quarter ended June 30, 2021 (the "2Q2021 10-Q"). The 2Q2021 10-Q was signed by, and contained SOX certifications substantively the same as those referenced in ¶ 117 above from, Defendants Tabuteau and Pizzie.

167. The 2Q2021 10-Q contained substantially the same statements referenced in ¶¶ 136-39 above from the 1Q2020 10-Q, which were false and misleading for the same reasons described therein, except that the 2Q2021 10-Q now updated its description of AXS-07 to note that its NDA had been submitted, by stating that "[w]e have completed two Phase 3 trials of AXS-07 for the acute treatment of migraine, which we refer to as the MOMENTUM and INTERCEPT trials. AXS-07 achieved the co-primary endpoints in both the MOMENTUM and INTERCEPT trials. An NDA has been submitted for filing for AXS-07 for the acute treatment of migraine supported by the positive results from the MOMENTUM and INTERCEPT trials. An open-label, long-term, safety study of AXS-07 in patients with migraine known as the MOVEMENT trial has also been completed. In the MOVEMENT trial, administration of AXS-07 resulted in rapid, and substantial relief of migraine pain and associated symptoms and was well tolerated with long term dosing."

168. These updated statements in the 2Q2021 10-Q were materially false and/or misleading for the reasons set forth in ¶ 108(i), (iii)-(iv), including because they misrepresented the likelihood that the FDA would approve the NDA for AXS-07 in light of the CMC problems that plagued the development of AXS-07.

169. On September 14, 2021, Axsome issued a press release by Defendant Jacobson and filed on a Form 8-K signed by Defendant Tabuteau, announcing that the FDA had accepted the AXS-07 NDA, stating:

> [T]he [FDA] has accepted for filing the Company's [NDA] for AXS-07 for the acute treatment of migraine, and has set a [PDUFA] target action date of April 30, 2022 for the NDA. AXS-07 (MoSEIC™ meloxicam-rizatriptan) is a novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine for migraine.
>
> "The FDA's acceptance of the NDA for AXS-07 is an important milestone for Axsome as it brings us closer to potentially making this multi-mechanistic treatment available to migraine patients in need," said [Defendant] Tabuteau, MD, Chief Executive Officer of Axsome. "We look forward to continued interactions with the FDA during the review process."
>
> The NDA is supported by results from two Phase 3 randomized, double-blind, controlled trials of AXS-07 in the acute treatment of migraine, the MOMENTUM and INTERCEPT trials, which demonstrated statistically significant elimination of migraine pain with AXS-07 compared to placebo and active controls.

170. The statements referenced in ¶ 169 above were materially false and/or misleading for the reasons set forth in ¶ 108(i), (iii)-(iv), including because they misrepresented the likelihood that the FDA would approve the NDA for AXS-07 in light of the CMC problems that plagued the development of AXS-07.

171. On November 8, 2021, Axsome issued a press release by Defendant Jacobson, and filed with the SEC on a Form 8-K signed by Defendant Tabuteau, reporting the Company's third quarter 2021 results. That press release quoted Defendant Tabuteau, who represented:

> Over the past several months we have continued to advance our differentiated late-stage CNS product candidates aimed at meaningfully improving the lives of

> patients . . . . [T]he NDA for AXS-07 in migraine was accepted, positioning Axsome to potentially commercialize two new treatments in the near to intermediate term for patients living with . . . serious CNS disorders[.]

172. That same day, Axsome hosted a conference call with investors and analysts to discuss the Company's third quarter 2021 results. On that call, in response to an analyst question regarding the FDA's need to delay the inspection of the contract manufacturing facility for AXS-07 that Axsome had announced that day,[14] Defendants Tabuteau and Laliberte downplayed the issues with manufacturing on the drug's regulatory timeline. That exchange read:

> **[SVB Leerink Analyst]**
>
> Just one quick question on the migraine, can you just help us understand, did you say that one of the two manufacturing sites might not be able to be signed off on by the PDUFA date? So you're implying that one could be and is one enough? Do you both have to be filed? I was a little confused by your comment. Thank you.
>
> **[Defendant] Tabuteau**
>
> Yes. So it's – I'll turn it over to [Defendant Laliberte], who will respond to that. But I think it's pretty straightforward in terms of what the FDA is trying to give a sense on there.
>
> **[Defendant] Laliberte**
>
> Thanks for that question. So there are obviously multiple manufacturing sites involved in the process for AXS-07. The FDA notified us that one specific manufacturing location that is based in the United States is required to have an inspection prior to them, as part of the review process.
>
> And then they did notify us that because of COVID-related restrictions, that may be in jeopardy of happening before the PDUFA date. So it's just this one manufacturer based in the United States that they specifically notified us of in their communication.

[14] Axsome announced on November 8, 2021, that "[t]he FDA notified the Company that, due to COVID-19 pandemic-related travel restrictions, they may be unable to complete a required inspection of a contract manufacturing facility [for the AXS-07 NDA] . . . prior to the PDUFA date[.]"

173. Also on this November 8, 2021 call, Defendant Laliberte downplayed the issues with AXS-07's manufacturing in the following exchange with an analyst:

> **Myles Minter**
>
> Okay, cool. Final one for me is just the NDA filing for 07, does that carry the same analytical measures on the manufacturing level as 05 in the current filing?
>
> **Herriot Tabuteau**
>
> Kevin?
>
> **Kevin Laliberte**
>
> Because the products are distinct molecules with different active components, they would not carry over necessarily into the 07 application specifically.

174. The statements referenced in ¶¶ 171-73 above were materially false and/or misleading for the reasons set forth in ¶ 108(i) and (iii)-(iv), including because they misrepresented Axsome's ability to "potentially commercialize" AXS-07 "in the near to intermediate term" and misrepresented the status of CMC issues with AXS-07, including by discussing the topic of the manufacturing of AXS-07 while failing to disclose the CMC issues that plagued the development of the drug.

175. Also on November 8, 2021, Axsome filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2021 (the "3Q2021 10-Q"). The 3Q2021 10-Q was signed by, and contained SOX certifications substantively the same as those referenced in ¶ 117 above from, Defendants Tabuteau and Pizzie.

176. The 3Q2021 10-Q updated the description of AXS-07 to note that in addition to the NDA for AXS-07 purportedly being "supported by the positive results from the MOMENTUM and INTERCEPT trials," the NDA was "accepted for filing by the FDA with a PDUFA target action date of April 30, 2022."

177. Other than this update, the 3Q2021 10-Q contained substantially the same statements referenced in ¶¶ 167-68 above from the 2Q2021 10-Q, that were false and misleading for the same reasons described therein. In addition, by noting the upcoming PDUFA date, the statements in the 3Q2021 10-Q even further misled investors by failing to disclose the problems with the manufacturing of AXS-07 that would preclude FDA approval by that date.

178. On March 1, 2022, Axsome issued a press release by Defendant Jacobson, and filed with the SEC on a Form 8-K signed by Defendant Tabuteau, reporting the Company's fourth quarter and full year 2021 results. That press release stated:

> Axsome's NDA for AXS-07 for the acute treatment of migraine is currently under review by the FDA with a PDUFA target action date for the NDA of April 30, 2022. The FDA previously notified the Company that, due to COVID-19 pandemic-related travel restrictions, they may be unable to complete a required inspection of a contract manufacturing facility, located in the United States, prior to the PDUFA date. ***Axsome has since been informed by the FDA that it does not anticipate any issues with completing this facility inspection prior to the AXS-07 PDUFA date***.

179. The same March 1, 2022 press release quoted Defendant Tabuteau as stating that "2021 was a year of continued progress which has put us in a position to potentially launch two new investigational medicines for patients living with depression and migraine," including "the April 30 PDUFA date for our NDA for AXS-07 in the acute treatment of migraine [that] is approaching."

180. The statements referenced in ¶¶ 178-79 above were materially false and/or misleading for the reasons set forth in ¶ 108(i) and (iii)-(iv), including because they misrepresented Axsome's ability to "launch" AXS-07 and discussed the imminent PDUFA date for AXS-07 while failing to disclose the CMC problems that plagued the development of the drug and made the FDA unlikely to approve the NDA for AXS-07.

181. Also on March 1, 2022, Axsome filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2021 (the "2021 10-K"). The 2021 10-K was signed by, and contained SOX certifications substantively the same as those referenced in ¶ 117 above from, Defendants Tabuteau and Pizzie.

182. The 2021 10-K contained substantially the same statements referenced in ¶¶ 158 and 176-77 above from the 2020 10-K and from the 3Q2021 10-Q, that were false and misleading for the same reasons described therein.

183. Among the false and misleading statements described above are several statements that Defendants repeated verbatim in every periodic SEC filing that Axsome made during the Class Period. These statements were particularly false and misleading because Defendants continued to tell investors the same refrains about the Company's business without providing any updates concerning the specific problems that Axsome was experiencing with the manufacturing of AXS-07.

184. For example, as described further above, Axsome disclosed in every annual 10-K that it filed during the Class Period that "[w]e believe that our existing suppliers of our product candidate active pharmaceutical ingredients and finished products will be capable of providing sufficient quantities of each to meet our clinical trial supply needs." This statement was particularly false and misleading because Defendants knew about manufacturing problems with Axsome's "existing suppliers" for a planned study and therefore did not "believe that our existing suppliers . . . will be capable of providing sufficient quantities of each to meet our clinical trial supply needs."

185. Similarly, Axsome provided the disclosures in every annual 10-K and quarterly 10-Q that "[i]f the manufacturers upon whom we rely fail to produce our product candidates in the

volumes that we require on a timely basis, . . . we may face delays in the development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues" and that "[i]f our existing third-party manufacturers, or the third parties that we engage in the future to manufacture a product for commercial sale or for our clinical trials, should cease to continue to do so for any reason, we likely would experience delays in obtaining sufficient quantities of our product candidates for us to meet commercial demand or to advance our clinical trials while we identify and qualify replacement suppliers." While Axsome framed these statements as "risks related to our dependence on third parties," they were materially misleading because Defendants described them as potential future issues when, in fact, Axsome was already experiencing precisely these problems with its third-party manufacturer for AXS-07.

VI. THE TRUTH BEGINS TO EMERGE

186. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class.

187. Throughout the Class Period, the price of Axsome securities was artificially inflated and/or maintained at an artificially high level as a result of Defendants' materially false and misleading statements and omissions identified herein.

188. The price of Axsome's securities significantly declined when the misrepresentations made to the market, and/or the information and risks alleged herein to have been concealed from the market, and/or the effects thereof, materialized and/or were revealed, causing investors' losses. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Axsome's securities, Plaintiffs and other Class members have suffered significant losses and damages.

189. In particular, the corrective disclosures described below revealed that despite Defendants' many misrepresentations concerning the purportedly strong support for the submission and approval of the NDA for AXS-07, problems with Axsome's manufacturing process for AXS-07 caused the Company to delay the submission of the NDA and then caused the FDA to issue a CRL for the NDA.

190. Before the market opened, on November 5, 2020, Axsome issued a press release reporting its third quarter 2020 results. The press release disclosed that "Axsome now plans to submit the [AXS-07] NDA to the FDA in the first quarter of 2021, versus previous guidance of the fourth quarter of 2020, to allow for inclusion of supplemental manufacturing information to ensure a robust submission package."

191. On this news, Axsome's stock price fell $5.22 per share, or 6.99%, to close at $69.51 per share on November 5, 2020 on trading volume that was over twice the 20-day moving average.

192. This news, however, did not reveal to investors the nature or extent of the CMC problems that Axsome was having with AXS-07. Despite this decline in the Company's stock price, Axsome securities continued to trade at artificially inflated prices because Defendants continued to misrepresent the CMC issues with the AXS-07 NDA.

193. On April 25, 2022, before the market opened, Axsome filed a Form 8-K with the SEC, which disclosed:

> On April 22, 2022, Axsome . . . was informed by the [FDA] that [CMC] issues identified during the FDA's review of the Company's [NDA] for its AXS-07 product candidate for the acute treatment of migraine are unresolved. Based upon the time remaining in the NDA review cycle, the Company expects to receive a [CRL] with respect to this NDA on or about the [PDUFA] target action date of April 30, 2022.

194. On this news, Axsome's stock price plunged $8.60 per share, or 21.99%, to close at $30.50 per share on April 25, 2022 on trading volume that was over 2.7 times the 20-day moving average.

195. The abundant analyst commentary described above shows how surprised investors were to learn that the FDA would not be approving the NDA for AXS-07 because of CMC issues. (*See supra* ¶¶ 57, 90-93).

196. For example, William Blair published a report that described this news as "obviously disappointing," noting that the stock is down 24% premarket.

197. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Axsome's securities, Plaintiffs and other Class members have suffered significant losses and damages.

VII. ADDITIONAL SCIENTER ALLEGATIONS

198. Defendants each had scienter as to the false and misleading nature of their statements because they each knew or, at a minimum, recklessly disregarded the facts described above in the Substantive Allegations section of this amended complaint.

199. Defendants Tabuteau and Pizzie's actual knowledge of the falsity of the alleged misstatements and omissions is also established by their signing of the SOX certifications, that certified each of Axsome's SEC filings, among other things, "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report"; fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended"; and that "[t]he information contained in [them] fairly presents, in all material respects, the financial condition and results of operations of the Company."

Before vouching for the accuracy of the statements made in Axsome's SEC filings, the certifying Defendants were obligated to familiarize themselves with the contents of the filings and Axsome's the underlying operations described therein.

200. Defendants' scienter is further established by Axsome's announcement on November 5, 2020 that "Axsome now plans to submit the [AXS-07] NDA to the FDA in the first quarter of 2021, versus previous guidance of the fourth quarter of 2020, to allow for inclusion of supplemental manufacturing information to ensure a robust submission package."

201. Defendants Tabuteau and Jacobson in particular had knowledge of these manufacturing issues because they discussed this issue on the Company's conference call that day, including Tabuteau noting the continued "manufactur[ing of] additional batches of drugs."

202. Defendants Tabuteau and Jacobson also showed their knowledge of the CMC issues with AXS-07 by discussing them on the Company's May 2, 2022 conference call following the FDA's issuance of its CRL.

203. In addition, Defendants' scienter is shown by Axsome's announcement on April 25, 2022 that the CMC issues that the FDA identified during its review of the Company's NDA for AXS-07 were "unresolved." This language indicates that the FDA had previously discussed these issues with the Company and provided this update in April 2022 because the problems remained unresolved.

204. Defendants' scienter is further established because they were on notice of CMC issues with AXS-07 based on the Company's similar prior experience with AXS-05. As analysts noted when the CMC problems with AXS-07 were announced on April 25, 2022, this was "déjà vu" because "[t]he Company ran into regulatory issues for its NDA of '05 for MDD," "***CMC***

deficiencies appear to be a persistent issue plaguing the company" and "***troubles in manufacturing seem to be a recurring theme with AXSM's drug candidates.***"

205. Defendants' scienter is further established by the FDA's description of their personal involvement in Axsome's drug development process. In June 2021, the FDA inspected one of Axsome's facilities.[15] Its report from this inspection, dated July 1, 2021, noted that Defendant Tabuteau "identified himself as the most responsible person" for the Company. In addition, Tabuteau told the inspector that "as the founder of Axsome Therapeutics, Inc., he is and has been involved[d] in almost every aspect associated with the development, implementation, and realization of [redacted] drug development projects." These responsibilities include, but are not limited to:

- "Correspondence and interaction with FDA regulatory officials";
- "Initial and continuing product development and regulatory strategies";
- "Clinical development and clinical trial outlook and implementation";
- "Protocol development and review";
- "Budget and finance";
- "IND and NDA filings"; and
- "Oversight [of] all company departments and personnel."

206. This inspection report also stated that as "the most responsible person," Defendant Tabuteau "has oversight over the following five key product development departments: [1] Quality assurance/product strategy, headed by executive VP Kevin J. Laliberte," (2) "Operations, headed by the chief operational officer, Mark l. Jacobsen," (3) "Clinical development, headed by senior

[15] A redacted copy of this inspection report is available on the website https://fdazilla.com/. CW 3 identified this inspection as related to AXS-05.

VP, Ms. Amanda E. Jones," (4) "Finance, headed by the chief financial officer" Nick Pizzie, and (5) "Commercial, headed by Lori A. Engelbert, Executive VP, commerce, and business development."

207. Defendants Jacobsen, O'Gorman, and Laliberte also participated in this inspection. The report described Jacobsen as the Company's Chief Operating Officer and Laliberte as its Executive Vice President of Product Strategy.

208. Defendant Laliberte told the inspector "that his responsibilities include overseeing multiple departments[,] including regulatory, chemistry manufacturing and controls, pharmacovigilance, supply chain, medical affairs, and research and operations." The report also noted elsewhere that individuals on the Company's CMC team report to Laliberte. Defendant Laliberte reports to Defendant Tabuteau.

209. The report described Defendant O'Gorman as the Senior Vice President of Medical Affairs who reports to Defendant Tabuteau. O'Gorman told the inspector that his "responsibilities include overseeing and providing medical monitoring services, safety meetings, and evaluation of adverse events and adverse events reports."

210. As noted above, CW 1 reported to the Executive Director of Clinical Research (Amanda Jones), the Director of Clinical Operations (Cheryl Askew), and the Senior Director of Clinical Operations (Caroline Streicher) at various points during CW 1's tenure at the Company. Jones, Askew, and Streicher all participated in the June 2021 FDA inspection.

211. The report described Jones as "one of the key points of" contact during the inspection. She told the inspector that her responsibilities included overseeing product development, "third party vendor qualification and management," and responsibilities related to clinical studies. Jones reports to Defendant Tabuteau.

212. This organizational structure corroborates CW 1's descriptions of the Company and shows even further that Defendant Tabuteau would be aware of the items that CW 1 observed.

213. Defendants' scienter is further shown by CW 1's assessment that executive management would have known about the equipment problems that Axsome's vendor was having with manufacturing AXS-07.

214. Furthermore, Defendants' scienter is corroborated by CW 1's observation that the Company's executive leadership appeared to prioritize profit over patients, they "cut corners," and they seemed to always be in a rush to meet milestones.

215. In addition, Defendants' scienter is further corroborated by a former employee who worked at Axsome from September 2018 to September 2021 in Clinical Operations ("CW 3") and reported to Amanda Jones, the Senior VP of Clinical Development. CW 3 had a senior role in Clinical Operations and participated in the June 2021 FDA inspection that was the subject of the report discussed above. CW 3 described Axsome's top leadership as "extremely secretive" and not forthcoming internally about Axsome's interactions with the FDA. CW 3 was not even told when the Company submitted its NDAs for AXS-05 and AXS-07. This clandestine attitude among Axsome's top leadership and their and unwillingness to share information internally regarding its NDAs and interactions with the FDA even with senior employees, demonstrate the senior executives' high level of personal involvement in these matters.

216. The Individual Defendants' scienter is also established because the alleged misstatements and omissions at issue here concerned Axsome's core operations. Indeed, Axsome described AXS-07 is one of its five products from its "core CNS portfolio." Moreover, AXS-07 is one of only two drugs for which Axsome had submitted an NDA through the Class Period, that Axsome planned to commercialize in the near future, and that contributed in any meaningful way

to market analysts' valuation of the Company. In addition, CMC issues are a crucial part of an NDA filing. Furthermore, the type of problems that CW 1 noted, where equipment problems prevented AXS-07's complex manufacturing process from operating for an extended period of time coinciding with the NDA submission for AXS-07, is the type of severe problem that would be brought to the attention of the Company's senior executives. Defendants, by virtue of their roles in senior management and involvement in the Company's core operations, would have had knowledge of the true nature of the Company's core businesses during the Class Period. In addition, Defendants had access to reports and communications describing these operations.

217. Axsome itself had scienter as to the false and misleading nature of the statements described above based on the knowledge of the Individual Defendants. In addition, because the false and misleading statements at issue here relate to one of the Company's core products, the Company's scienter can be inferred because these statements would have been approved by corporate officials that knew they were false or misleading.

VIII. NO SAFE HARBOR

218. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

219. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false

forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer or top management of Axsome who knew that the statements were false when made.

IX. CLASS ACTION ALLEGATIONS

220. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Axsome securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

221. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Axsome securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can be ascertained only through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Axsome or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

222. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

223. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests antagonistic to or in conflict with those of the Class.

224. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether Defendants' acts violated the federal securities laws as alleged herein;
- whether Defendants' statements to the investing public during the Class Period misrepresented material facts about the business, operations and management of Axsome related to the development of, and NDA for, AXS-07;
- whether the Individual Defendants caused Axsome to issue false and misleading statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading statements;
- whether the prices of Axsome securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

225. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

X. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET AND *AFFILIATED UTE* PRESUMPTIONS

226. Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Axsome securities are traded in an efficient market;
- the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- the Company's securities traded on the NASDAQ and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiffs and members of the Class purchased, acquired and/or sold Axsome securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

227. Based upon the foregoing, Plaintiffs and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

228. Alternatively, Plaintiffs and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

XI. COUNT I

A. (Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

229. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

230. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

231. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiffs and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Axsome securities; and (iii) cause Plaintiffs and other members of the Class to purchase or otherwise acquire Axsome securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

232. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Axsome securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Axsome's finances and business prospects, including AXS-07.

233. By virtue of their positions at Axsome, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiffs and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose

such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

234. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Axsome, the Individual Defendants had knowledge of the details of Axsome's internal affairs.

235. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Axsome. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Axsome's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Axsome securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Axsome's business and financial condition which were concealed by Defendants, Plaintiffs and the other members of the Class purchased or otherwise acquired Axsome securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

236. During the Class Period, Axsome securities were traded on an active and efficient market. Plaintiffs and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired Axsome securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiffs and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiffs and the Class, the true value of Axsome securities was substantially lower than the prices paid by Plaintiffs and the other members of the Class. The market price of Axsome securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiffs and Class members.

237. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

238. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented statements to the investing public.

XII. COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

239. Plaintiffs repeat and re-allege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

240. During the Class Period, the Individual Defendants participated in the operation and management of Axsome, and conducted and participated, directly and indirectly, in the conduct of Axsome's business affairs. Because of their senior positions, they knew the adverse non-public information about Axsome's statements described above.

241. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Axsome's financial condition and results of operations, and to correct promptly any public statements issued by Axsome which had become materially false or misleading.

242. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Axsome disseminated in the marketplace during the Class Period concerning Axsome's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Axsome to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Axsome within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Axsome securities.

243. Each of the Individual Defendants, therefore, acted as a controlling person of Axsome. By reason of their senior management positions and/or being directors of Axsome, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Axsome to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Axsome and possessed the power to control the specific activities which comprise the primary violations about which Plaintiffs and the other members of the Class complain.

244. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Axsome.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiffs and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

XIV. DEMAND FOR TRIAL BY JURY

Plaintiffs hereby demand a trial by jury.

Dated: October 7, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2022, a copy of the foregoing was filed electronically via the Court's CM/ECF system. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

/s/ Michael Grunfeld
Michael Grunfeld